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EFECE: A New Locking and Compressing Device with Kirschner-Wire. A Biomechanical Evaluation of the EFECE System on Tibia Plateau Fracture Simulation

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Abstract

Background: This study aims to introduce a new Kirschner-wire (K-wire) locking and compressing implant called EFECE, and to evaluate the EFECE system biomechanical resistance on medial tibia plateau fracture simulation.

EFECE implants are cylinder-shaped with 5 mm length, 8 mm radius and there is a hole for insertion of a 1.2 mm K-wire. The implant comprises two pieces attached to each other with threads. Inside these implants are gloves for the insertion of three magnetically active balls. The locking mechanism is applied with the help of the balls in the cone-shaped gloves.

A medial plateau fracture was simulated in sheep tibia. After reduction, first a 1.2 mm K-wire and then two EFECE implants were reciprocally inserted at the distal end of the fracture line to function as a buttress. Second and third K-wires were inserted at least 0.5 mm away from the joint line, and two pairs of reciprocal EFECE implants pulled on these two K-wires, and then the EFECE implants were compressed and tightened using a hand set. Increasing vertical compression force was applied to these systems. The maximum force and displacement were evaluated.

Results: After 10 experiments, there were no EFECE implant failures on the K-wires. The mean maximum force was 2509 Newton (1706-2999N). The mean displacement was 22.5 mm (15 mm to 31 mm).

Conclusion: The EFECE system fixation in tibia medial plateau fracture simulation is sufficient and can be used for fracture fixation. Compression along the K-wires, percutaneous surgical technique, and implant removal with magnets may change our surgical daily practice.

Keywords: Fracture fixation; Internal fixators; Bone wires; Tibial plateau fracture; Osteosynthesis

Abbreviations

K-Wire: Kirschner Wire; N: Newton; LCP: Locking Compression Plate

Introduction

Proximal tibia fractures constitute approximately 1.2% of all fractures [1]. The management of tibial plateau fractures remains challenging. Operative techniques attempt to restore the articular surface to regain and maintain optimal function in the joint after injury. The goals of reconstruction are articular congruity, restoration of anatomic alignment, and joint stability to allow early joint motion and weight bearing. These goals are balanced against the challenge of preserving the local biological environment.

Controversy surrounding best practices for the management of these fractures has resulted in a variety of fixation methods, designed to address variations in specific fracture patterns, integrity of the soft-tissue envelope, and bone quality. Traditional options for fixation include the use of K-wires, screws, plates, and hybrid external fixators. Each of these techniques aims to keep fracture fragments in the desired position until healing has occurred. The advantages and disadvantages of these techniques vary according to fracture type, and influence the treatment plan of the surgeon.

Most authors advocate reduction and internal fixation when articular step is ≥ 2 mm to 3 mm, instability is >5° to 10° in full extension, and to prevent tibia plateau widening during fracture consolidation [2-4]. Different methods for fracture fixation have been defined, including the use of

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3.5 mm to 4.5 mm cortical lag screws, 6.5 mm cancellous lag screws, and compression or locking proximal tibia plates. These surgical approaches are made with percutaneous, arthroscopic, or open techniques. Soft tissue injury, bone quality, patient age, displacement, and post-traumatic arthritis are important factors influencing the outcome of proximal tibia fracture treatments.

Proximal tibia fractures have a negative impact on self-reported quality of life and physical activity levels within the first year following fixation when compared with preoperative levels [5]. The ideal implants and fixation techniques for tibia plateau fractures are still evolving. This study seeks to contribute to this evolution through examination of the EFECE System for proximal tibia fractures.

EFECE implants are newly-patented devices for fracture fixation. They allow only forward movement on K-wires. Due to the locking mechanism, the implants catch the K-wire when pulling back and do not allow backward movement [6]. When EFECE implants are inserted reciprocally on K-wire and then wire tension is applied, they compress the fracture line. After locking the EFECE implants, there can be no backward or forward movement on the K-wires. The presence of magnetically active balls in the locking mechanism enables removal of these implants with magnets; the magnetic force prompts the balls to move back to the base of the cone and release the k-wire.

This article describes the biomechanical behavior of EFECE systems for the compression and fixation of tibia plateau fractures. The aim of this study is to document the fixation strength of these EFECE Systems against compression forces in medial tibia plateau fracture simulation.

Materials and Methods

Approval from the Ethics Review Board was not required due to the non-human subject nature of this study; all proper laboratory protocols were followed in completion of this study.

The surgical kit for EFECE systems, which includes a sleeve, working cannula, screwdrivers, K-wire tensioner, wire cutter, and magnet, is designed for a percutaneous surgical technique. After reduction of the fracture and K-wire placement conducted through conventional techniques, two reciprocal EFECE implants are pushed forward on K-wires until contact is made with the bone cortex, using the sleeve, working cannula, and screwdrivers. Systems reconstructed on the fracture line with two of these devices and a K-wire may function as a buttress in fracture treatment. Compression force is then applied on the fracture fragments with K-wire tensioning using the K-wire tensioner. After locking the implants with screwdrivers, these devices do not allow forward or backward movement on the K-wires. The remaining part of the K-wire is cut with the percutaneous wire cutter.

The prototype of this device (EFECE, Micron Medical, Ankara, Turkey) is cylinder-shaped with an 8 mm radius and a length of 5 mm and contains a hole for insertion of a 1.2 mm K-wire. The implant comprises two pieces attached to each other with threads. The top piece functions as a cap. The second piece contains three gloves for the insertion of three magnetically active balls, each with a 2.5 mm radius. The angle of the cone-shaped gloves to the K-wire axis is 7º (Figure 1).

Figure 1: The EFECE implant contains two pieces that are attached to each other with threads. The top piece functions as a cap. The second piece contains 3 gloves for the insertion of 3 balls. These balls are 2.5 mm radius and magnetic active. The angle of the cone shaped gloves to the K-wire axis is 7º. There is a hole for insertion of a 1.2 mm K-wire in each piece.

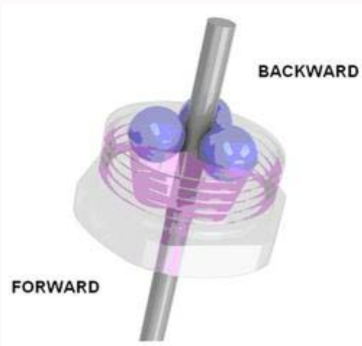

Figure 2: The EFECE implant locking mechanism is applied with the help of balls in the cone shaped gloves. In forward movement to compress the fractured fragments across the K-wire, the balls move back to the base of the cone and release the K-wire. During pulling back, the balls move to the narrow part of the cone and lock the K-wire.

The EFECE implant locking mechanism is activated through the balls in the cone-shaped gloves. In forward movement, the balls move back to the base of the cone and release the K-wire. During the pulling back movement, the balls move to the narrow part of the cone and lock the K-wire (Figure 2).

To define the locking strength of the EFECE implants for medial tibia plateau fracture simulation, 10 rear leg tibias of sheep aged 1 to 2 years were used. The animals were sacrificed under veterinary supervision. Each tibia was cut transversely from the diaphysis and fixed to a plate with synthetic cement. From the proximal articular surface of the tibia, a vertical osteotomy was applied 1 cm from the medial side of the tibia plateau. After reduction of this fracture simulation, the first 1.2 mm stainless–steel K-wire (Sayan Medical, Izmir, Turkey) was inserted from the distal end of the fracture line, and then two reciprocal EFECE implants were inserted on this K-wire. These EFECE implants were compressed and tightened on the K-wire from both sides using a wire tensioner and a hand set. This K-wire placement functioned as a buttress. Second and third K-wires were inserted 0.5 mm away from and parallel to the articular surface. On each of these two K-wires, two pairs of EFECE implants were pushed reciprocally as far as the bone cortex, and then the EFECE implants were compressed and tightened from both sides using a wire

Figure 3: The EFECE system was attached to the jaws of the material testing system servo hydraulic testing machine and increasing compression force was applied to these systems.

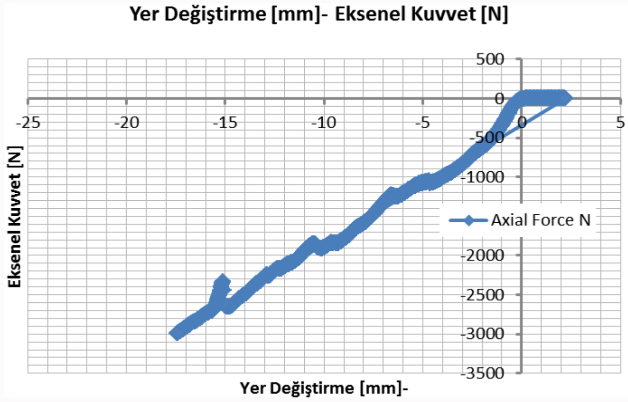

Figure 4: Increasing compression force was applied to these implants until failure. The maximum force and the total extension at the time of failure were evaluated.

tensioner and hand set.

The fracture fixation system was then attached in the jaws of the Material Testing System (Instron Inc, Norwood, Massachusetts, USA) servo hydraulic testing machine (Figure 3). Increasing compression force of 2 mm/min was applied to the implants until failure. Maximum force and total extension at the time of failure were evaluated using Nexygen software (Figure 4).

Results

There was no EFECE implant failures on K-wires in any of the 10 experiments conducted on medial tibia plateau fracture fixation through use of the EFECE system. The mean maximum compression force that the EFECE system could resist was 2509 N (1706 N to 2999 N). The mean displacement at this maximum force was 22.5 mm (15 mm to 31 mm). In all experiments, failure of the system was due to the breakup of the fragments, which was caused by the K-wires cutting through the fragments.

Discussion

With the newly patented EFECE Systems, fractures can be treated with an internal fixation technique. In fixation with K-wires, after reduction of the fracture, the fragments are fixed by passing straight wires through the bone fragments. In 1996 Beris et al. [7] showed that subchondral K-wire reinforcement of tibial plateau depressions significantly enhanced load tolerance. This suggested that a subchondral cluster of K-wires in the treatment of tibial plateau fractures may protect the articular cartilage from the loss of reduction resulting from forces applied to the knee during non-weight-bearing motion. The most important restriction of this technique is that forward/backward movement of the fractured fragments along the wire can result in malunion or non-union [8]. After reduction, the wires do not provide compression between the fracture fragments. In addition, the wires may migrate after they have been placed into the bone [9].

Cavusoglu et al. [10] compared the reciprocal olive wire method with the divergent wire stretching method on tibia models in a biomechanics laboratory. No distinct difference was observed between the classic olive wire stretching method and the divergent wire stretching method in respect to preservation of the interfragmentary compression under the application of weight. The divergent wire stretching method using 800 N of wire tensioning was significantly superior in achieving homogeneous interfragmentary compression. In the same study, clinical results were reported for 34 patients treated with the Ilizarov technique. The divergent wire stretching technique was used in all cases. No other surgical intervention was required for non-union or reduction failure. More than 2 mm separation was detected in 12 cases during a 24-week observation period, but this was not considered clinically significant. In 29 cases, the knee range of motion was 0° to 135° degrees.

In the fixation of tibia plateau fractures with screws, first, the fractured fragments are reduced, and then screws are inserted to hold the fragments in the desired position. In the working mechanism of these screws, compression is obtained between fragments by creating mutual forces between the screw head and the screw threads [11]. In the screw insertion technique, the size of the screw is increased to increase compression force and fixation strength between the fragments. However, when bone fragments are small, it may not be possible to increase screw size, and there may not be enough space between the fragments to insert additional screws.

In the surgical technique using conventional screws, first the bone is drilled for the screw core using a drill, then tapping is performed for the screw threads. Then, the screws are placed. Before these procedures, sometimes a K-wire has to be placed to provide additional guidance for the cannulated screw. Consequently, the surgical technique is relatively difficult. Furthermore, attempting to provide fixation with screw threads may not be possible for patients with osteoporosis. Screws for osteoporotic bone fracture fixation may not be able to obtain sufficient purchase between the fragments [12].

In the fixation of fractures with plate and screws, after reduction, the fracture fragments are fixed by means of plates attached with screws. Since plate attachment is performed with screws, this procedure carries with it all the disadvantages of screw application. Plate placement requires more peripheral soft tissue to be stripped, which means more incision and more vascularization problems for bone fragments [13]. The plate may hinder skin closure in areas with thin subcutaneous tissue, and plates may be palpable. Plate placement may not be possible when bone fragments are small or close to the joint. In addition, after fracture treatment, bone and peripheral tissues are re-damaged during plate removal, causing well defined complications [14].

Kojima K et al. [15] biomechanically compared the interfragmentary compression of cancellous and cortical lag screws and angle stable locking plates in osteoporotic and non-osteoporotic synthetic human bone models of tibia plateau fractures. A comparison was made of 2 mm × 6.5 mm cancellous lag screws with washers, 4 mm × 3.5 mm cortical lag screws, and a 3.5 mm LCP (locking Compression Plate) proximal lateral tibia plate.

With each technique, pressure was recorded along the articular osteotomy gap, and the mean pressure of each sample was calculated. It was reported that both lag screw techniques exhibited comparable interfragmentary compression in non-osteoporotic bone. Interfragmentary compression in osteoporotic bone was not significantly different using lag screws. The amount of interfragmentary compression was similar in both groups under comparison of the four cortical lag screw fixations in non-osteoporotic and osteoporotic bone. Fixation with two cancellous screws exhibited significantly higher compression in non-osteoporotic bone compared to osteoporotic bone.

With the EFECE systems, fixation and compression can be achieved independently of bone density. In forward movement, the balls move back to the base of the cone and release the k-wire. During pulling back, balls move to the narrow part of the cone and lock the k-wire. The bone has no role in this locking mechanism. The fixation system of these devices may function as a "bag of bones," which would make it a new option suitable for osteoporotic patients.

Weimann et al. [16] studied a porcine model of lateral tibial plateau fracture simulation. In the first group, conventional two-screw reconstruction was applied. In the second group, two screws were used as in the conventional technique, and then an anterior posterior positioned additional screw was added perpendicular to these screws, in what is known as the "jail technique." Vertical compression force was applied to these systems, as in the current study. After 40 experiments, the jail technique showed a significantly higher mean maximum load (2275.9 N) in comparison to the conventional reconstruction (1796.5 N, $p<0.001$) in load-to-failure testing. It was concluded that the jail technique may be a feasible alternative to conventional screw osteosynthesis in minimally invasive reconstruction of lateral tibial plateau fractures. A potential advantage of the jail technique is the prevention of screw cut-outs through the cancellous bone. In the current study with the same compression load-to-failure protocol, the mean maximum force was 2509 N (1706 N to-2999 N). This mean maximum force is more than the values that Weimann et al. [16], obtained in their study for the jail technique or conventional technique.

EFECE implants may function as a K-wire fixation system for small and close to the joint line fracture fragments because fixation and compression that cannot be achieved with screws that we use in daily practice can be achieved with thin K-wires. These also function as screws for compression of the fracture fragments over K-wires. With this new fixation technique, fractures in anatomic locations where screw placement is difficult, such as the elbow, may be treated with thin K-wires with compression. The use of two EFECE devices and a K-wire enables compression and fixation of the fractured fragments.

The presence of magnetically active balls in the locking mechanism enables removal of these implants with magnets; the magnetic force prompts the balls to move back to the base of the cone and release the k-wire. This implant removal technique presents an easy and new approach to orthopedic surgery.

In the current study, the mean displacement was 22.5 mm (15 mm to 31 mm). This value may seem too high for osteosynthesis. However, we did not define a cut-off point for the maximum force or the displacement in order to define the biomechanical behavior of these new implants until failure. It was decided to define the limits of this technique.

There are limitations of EFECE Systems. The EFECE system needs at least two reciprocal EFECE implants for a K-wire fixation. The counterpart of the K-wire that goes through the fragments and leaves the bone cortex needs to be prepared for EFECE insertion. With EFECE Systems, the fixation strength is dependent on the mechanical properties of a thin K-wire.

Limitations

There were also some limitations of this study. The biomechanical properties of sheep tibias are similar to human bone, but they are not human specimens. Testing along a single axis cannot appropriately simulate physiological loading at the fracture site. Furthermore, the specimens were tested with the load applied to the medial tibial plateau. This type of loading is not entirely physiological and does not reproduce the complex loading of the tibial plateau. As this is a new technique, we do not have information about the amount of compression force that can be applied using wire tensioning. These unknown data will be examined in the next study.

More study is needed to confirm the efficacy of EFECE systems as fixation techniques due to the newness of the procedure. However, these results provide initial validation of EFECE Systems as an effective new implant technology for the repair of fractures.

Conclusion

This study can be considered a step forward for a new fixation technique definition in orthopedic surgery. This technique could be a milestone for better fixation with minimal invasive surgery effort. If EFECE Systems are successful, small bone fragments, osteoporotic bone fractures, and anatomic locations where screw placement is difficult may be treated more easily with these new implants. Moreover, the implant removal with magnets will make implant removal simpler and minimally invasive.

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